Announcement of Federal Funding Opportunity

Summary

I. GENERAL INFORMATION

A. Title of Award: Physician-Scientist Training Award (PHYS).

B. Program Name: Department of Defense (DOD) Fiscal Year 2003 (FY03) Breast Cancer Research Program (BCRP).

C. Funding Opportunity Number: DAMD17-BC03-PHYS.

D. Agency Name: US Army Medical Research and Materiel Command (USAMRMC), Office of the Congressionally Directed Medical Research Programs (CDMRP), 1077 Patchel Street, Fort Detrick, Maryland 21702-5024.

E. Agency Contact(s)

1. Questions related to the Program, proposal format, or required documentation may be addressed to the CDMRP at:

Phone:	301-619-7079
Fax:	301-619-7792
E-mail:	cdmrp.pa@det.amedd.army.mil
Mail:	Commander US Army Medical Research and Materiel Command ATTN: MCMR-PLF (DAMD17-BC03- PHYS) 1077 Patchel Street (Building 1077) Fort Detrick, MD 21702-5024

2. Questions related to electronic submission: The help line phone numbers are provided on the web or may be requested by e-mail as follows:

Website:	https://cdmrp.org/proposals (the proposal submission website)
E-mail:	help-proposals-cdmrp@cdmrp.org

F. Anticipated Instrument Type(s): Grants/Cooperative Agreements.

G. Catalog of Federal Domestic Assistance (CFDA) Number(s): 12.420; Military Medical Research and Development.

H. Website Address to Access Application Package: Proposals must be submitted electronically at https://cdmrp.org/proposals. The website contains all the information, forms, documents, and links you will need to apply.

II. FUNDING OPPORTUNITY DESCRIPTION

The intent of the Physician-Scientist Training Award is to provide a mentored training experience that will prepare physicians for active careers in clinical breast cancer research.

III. AWARD INFORMATION

- Type of award: grant/cooperative agreement.
- A total of approximately $5M is available for this award mechanism.
- Depending on the number and quality of the applications, it is anticipated that approximately seven proposals will be funded.
- Funding for Physician-Scientist Training Awards can be requested for up to a maximum of $700,000 inclusive of direct, indirect, and tuition debt reduction costs over the life of the award. Please see the Full Text of the Program Announcement (page 4) description for additional details regarding funding.
- Physician-Scientist Training Awards require a 5-year commitment to clinical breast cancer research and consist of two phases.

IV. ELIGIBILITY INFORMATION

A. Applicants: Eligible applicants for the Physician-Scientist Training Award are physicians in the last year of oncology graduate medical education or within the first 3 years as a junior faculty member. Additionally, Physician-Scientist Training Award applicants must be US citizens or permanent residents.

B. Institutions: Eligible institutions include for-profit, non-profit, public, and private organizations within the United States.

C. Cost Sharing: Not required.

D. Other Eligibility Criteria: Please see the Full Text of the Program Announcement description for details regarding duplicate submissions, applications from Historically Black Colleges and Universities/Minority Institutions, and administrative compliance issues.

V. PROPOSAL PREPARATION AND SUBMISSION INFORMATION

A. Proposal Information: Applicants are required to submit the Proposal Information prior to upload of the proposal. Complete the Proposal Information as described at https://cdmrp.org/proposals.

B. Proposal Preparation: All proposals must be converted into an electronic PDF (Portable Document Format) file for electronic proposal submission. Please see the Full Text of the Program Announcement description for details.

C. Submission Dates and Times: Deadline Date: May 14, 2003. Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant's institution's Sponsored Programs Office (or equivalent) by 5:00 p.m. (Eastern time).

D. Electronic Submission Requirements: Electronic submission is required. No paper copy submissions will be accepted. Proposals must be submitted electronically at https://cdmrp.org/proposals. Please see the Full Text of the Program Announcement description for details.

VI. PROPOSAL REVIEW INFORMATION

The CDMRP uses a two-tiered review process for proposals: scientific peer review, followed by programmatic review. Details of both tiers of review can be found in the Full Text of the Program Announcement.

VII. AWARD ADMINISTRATION INFORMATION

A. Award Notices and Administrative Requirements: Details of award notification procedures and administrative requirements including Regulatory Compliance and Quality documents (Certificate of Environmental Compliance, Research Involving Human Subjects and/or Anatomical Substances, Research Involving Animals, and Safety Program Plan) can be found in the Full Text of the Program Announcement.

B. Reporting Requirements: Annual reporting requirements apply.

VIII. OTHER INFORMATION

Details pertaining to Disclosure of Proprietary Information outside the Government, Government Obligation, Information Service, Inquiry Panel Review, and Title to Inventions and Patents can be found in the Full Text of the Program Announcement.

Full Text of the Program Announcement

I. GENERAL INFORMATION

A. Title of Award: Physician-Scientist Training Award (PHYS).

B. Program Name: Department of Defense (DOD) Fiscal Year 2003 (FY03) Breast Cancer Research Program (BCRP).

C. Funding Opportunity Number: DAMD17-BC03-PHYS.

D. Agency Name: US Army Medical Research and Materiel Command (USAMRMC), Office of the Congressionally Directed Medical Research Programs (CDMRP), 1077 Patchel Street, Fort Detrick, Maryland 21702-5024.

E. Agency Contact(s):

1. Questions related to the Program, proposal format, or required documentation. Applicants should submit questions as early as possible. Every effort will be made to answer questions within 5 working days.

Phone:	301-619-7079
Fax:	301-619-7792
E-mail:	cdmrp.pa@det.amedd.army.mil
Mail:	Commander US Army Medical Research and Materiel Command ATTN: MCMR-PLF (DAMD17-BC03- PHYS) 1077 Patchel Street (Building 1077) Fort Detrick, MD 21702-5024

2. Questions related to electronic submission: Help lines will be available to answer specific questions regarding the preparation of proposals for electronic submission, or the process of electronic submission. The help line phone numbers are provided on the web or may be requested by e-mail as follows:

Website:	https://cdmrp.org/proposals (the proposal submission website)
E-mail:	help-proposals-cdmrp@cdmrp.org

F. Anticipated Instrument Type(s): The USAMRMC implements its extramural research program predominantly through the award of grants and cooperative agreements. More information on these funding instruments may be obtained by request from:

Fax:	301-619-2937
E-mail:	q&a.baa@det.amedd.army.mil
Mail:	Director US Army Medical Research Acquisition Activity ATTN: MCMR-AAA 820 Chandler Street Fort Detrick, MD 21702-5014

G. Catalog of Federal Domestic Assistance (CFDA) Number 12.420: Military Medical Research and Development.

H. Website to Access Application Package: Proposals must be submitted electronically at https://cdmrp.org/proposals. This website will contain all the information, forms, documents, and links you will need to apply. If you experience difficulties in downloading documents, contact the CDMRP as indicated in Section I.E.1 above.

II. FUNDING OPPORTUNITY DESCRIPTION

A. Program History:

The Physician-Scientist Training Award is part of the DOD BCRP, which was established in FY92 to promote innovative research directed toward the eradication of breast cancer. Appropriations for the BCRP since FY92 total $1.38 billion (B). The program history of the FY92-02 BCRP is shown in Table 1. The FY03 appropriation is $150 million (M).

Table 1: History of the DOD's Peer Reviewed BCRP

Program History	FY92-00	FY01	FY02[1]
BCRP Congressional Appropriations	$1.05B	$175M	$150M
Total Proposals Received	15,017	1,500	1,883
Total Proposals Funded	2,837	380	308
Physician-Scientist Training Award Proposals Received	N/A[2]	N/A	18
Physician-Scientist Training Award Proposals Funded	N/A	N/A	9

[1]Award negotiations will be finalized by September 2003.
[2] N/A = Not applicable.

B. Program Objectives: The overall goal of the FY03 BCRP is to promote research directed toward eradicating breast cancer. Within this context, the objective of the BCRP is to fund a balanced portfolio of scientifically meritorious research related to all aspects of breast cancer. Proposals are sought across all areas of laboratory, clinical, behavioral, and epidemiologic research including all disciplines within the basic, clinical, psychosocial, behavioral, sociocultural, and environmental sciences; nursing; occupational health; alternative therapies; public health and policy; and economics. Additionally, proposals that address the needs of minority, low-income, rural, and other under-represented and/or medically underserved populations are encouraged.

The BCRP is challenging the scientific community to design innovative research that will foster new directions for, address neglected issues in, and bring new investigators to the field of breast cancer research. As in previous years, the central theme of the BCRP is innovation. Scientific ventures that represent underinvestigated avenues of research or novel applications of existing technologies are highly sought. Although the BCRP wishes to encourage risk-taking research, such projects must nonetheless demonstrate solid scientific judgment and rationale.

C. Award Mechanism Description: There is an urgent need to train physicians as breast cancer clinical researchers. Often, because of competing demands for a physician's time and the need to repay medical school costs, young physicians are not able to pursue clinical research careers. The intent of the Physician-Scientist Training Award is to address the critical shortage of physicians performing clinical breast cancer research.

Eligible applicants for the Physician-Scientist Training Award are physicians in the last year of oncology graduate medical education or within the first 3 years as a junior faculty member. This award is intended to provide a mentored training experience that will prepare physicians for active careers in clinical breast cancer research. The training program may include formal coursework and seminars that should provide the Principal Investigator (PI) with experience in key clinical research areas such as statistics, bioethics, molecular biology, and clinical trial design. The training must take place at an institution or organization within the United States where clinical research is performed. Key elements of this award are the involvement of a mentor that has an established cancer research program with an emphasis in clinical breast cancer research, and the aggressive protection of the PI's time. In addition, a key provision will be demonstration by the PI of an ongoing commitment to clinical breast cancer research. For the purposes of this award, breast cancer clinical research is defined as patient-oriented research involving human subjects or material of human origin (e.g., tissue specimens); research should involve direct interaction with human subjects and have demonstrable potential to impact prevention or treatment of breast cancer.

Physician-Scientist Training Award proposals should include a discussion of the level of institutional commitment to fostering the applicant's clinical breast cancer research career as reflected by (1) the extent the applicant will be relieved of his or her academic and/or other clinical responsibilities to have additional time for research, (2) the provision of adequate laboratory facilities and equipment to support the clinical research requirements, and (3) the opportunities for critical professional interaction with senior colleagues. **A letter of support from the institution must be included as part of the proposal.**

III. AWARD INFORMATION

Physician-Scientist Training Awards require a 5-year commitment to clinical breast cancer research and consist of two phases. During the initial phase, the first 3 years of the award, both salary support and a medical school debt reduction incentive are provided. The final 2-year phase provides continued medical school debt reduction payments contingent on the PI's ongoing commitment to clinical breast cancer research. The total support that can be requested over the life of the award is $700,000 inclusive of direct, indirect, and tuition debt reduction costs. The amount allotted for travel is $1,800 per year per PI to attend scientific/technical meetings. In addition, funding should be requested for a one-time, 3½-day meeting in 2005 to disseminate the results of DOD-sponsored research. Proposals requiring lower levels of funding may also be submitted. Please refer to section V.F.1 for information regarding salary support, loan repayment, and other funding restrictions associated with this award.

Depending on the quality and the number of proposals received, the CDMRP expects to allot approximately $5M of the $150M FY03 BCRP appropriation to fund approximately seven Physician-Scientist Training Awards.

IV. ELIGIBILITY INFORMATION

A. Applicants: Eligible applicants for the Physician-Scientist Training Award are physicians in the last year of oncology graduate medical education or within the first 3 years as a junior faculty member. Additionally, Physician-Scientist Training Award applicants must be US citizens or permanent residents.

B. Institutions: Eligible institutions include for-profit, non-profit, public, and private organizations within the United States. Examples include universities, colleges, hospitals, laboratories, companies, and agencies of local, state, and federal governments. The USAMRMC is especially interested in receiving applications from Historically Black Colleges and Universities/Minority Institutions (HBCU/MI).

C. Cost Sharing: Cost sharing is not a requirement for this award.

D. Other Eligibility Criteria:

1. Duplicate Submissions: Submission of the same research project to the FY03 BCRP under different award mechanisms is not allowed. This includes duplicate submissions under different award mechanisms by different PIs. The government reserves the right to reject duplicative proposals.

2. HBCU/MI: A goal of the DOD is to allocate funds for the CDMRP's peer reviewed research to fund proposals from HBCU/MI. This provision is based upon guidance from Executive Orders.[1] Proposals submitted to the DOD are assigned HBCU/MI status if the submitting institution is so designated by the Department of Education on the date that the program announcement is released. The Department of Education list is posted on the CDMRP website at http://cdmrp.army.mil/funding/pdf/mibcrp012703.pdf under Minority Institutions.

3. Administrative Compliance Issues: Compliance guidelines have been designed to ensure the presentation of all proposals in an organized and easy-to-follow manner. Peer reviewers expect to see a consistent, prescribed format for each proposal. Nonadherence to format requirements makes proposals difficult to read, may be perceived as an attempt to gain an unfair competitive advantage, and may result in proposal rejection or a lower global priority score.

Failure to comply with any of the five items listed below will result in administrative rejection of the entire proposal prior to peer review:

- Proposal body exceeds page limit.
- Proposal body is missing.
- Detailed cost estimate is missing.
- Proposal is submitted after the deadline.
- Required administrative documentation is not included.

For any other sections of a proposal with a defined page limit, any pages over the specified limit will be removed from the proposal and not forwarded for peer review.

Unless specifically requested by the CDMRP, any material submitted after the submission deadline will not be forwarded for peer review.

[1] Executive Orders 12876, 12900, and 13021

V. PROPOSAL PREPARATION AND SUBMISSION INFORMATION

A. Proposal Components Summary: This subsection is a summary of submission requirements. Details, URLs, and other links are provided in the appropriate subsections of this program announcement.

The PI is responsible for uploading the following information:

- **Proposal Information:** The Proposal Information consists of two parts, both of which are entered as data fields. A Letter of Intent is generated when a draft of Part 1 of the Proposal Information is saved.
- **Statement of Work (SOW) and Proposal Abstracts:** The SOW, Technical Abstract, and Public Abstract are each entered as a separate data field.
- **Proposal:** The proposal is uploaded as a PDF (Portable Document Format) file under the "File Upload" tab.
- **Budget Information:** The budget information is uploaded as a PDF file under the "File Upload" tab.
- **Regulatory Compliance and Quality (RCQ) Documents:** The Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance Form are each uploaded as separate PDF files under the "File Upload" tab.

The Contract Representative (or equivalent) from the applicant's institution is responsible for the following:

- **US Army Medical Research Acquisition Activity (USAMRAA) Documents:** The institute's currently negotiated Rate Agreement, Certifications and Assurances for Assistance Agreements, and the Representations for Assistance Agreements are to be uploaded as separate PDF files under the Contract Representative "My Profile" tab.
- **Approval:** The Contract Representative must provide approval of all proposal components (Proposal Information, SOW, Abstracts, Proposal, Budget Information, and RCQ documents). Contract Representative approval must occur prior to the submission deadline of 5:00 p.m. (Eastern time) May 14, 2003. Otherwise, the entire proposal will be considered a "LATE" submission and will not be forwarded for review.

B. Proposal Information: Applicants are required to submit the Proposal Information, Parts 1 and 2, (referred to in previous years as the Proposal Cover Booklet) prior to upload of the proposal and the budget information. Complete the Proposal Information as described in https://cdmrp.org/proposals. The Proposal Information must include the e-mail address of a representative from the applicant's Sponsored Programs Office who is authorized to negotiate on behalf of the institute.

- **Letter of Intent:** All applicants considering submission of a proposal in response to this program announcement are expected to submit an electronic Letter of Intent no later than 4 weeks prior to the May 14, 2003 deadline. To accomplish this, the applicant should complete Part 1 of the Proposal Information section at https://cdmrp.org/proposals, then save the information by clicking on the "Save and Forward Letter of Intent" button. This information may be changed at any time until the applicant submits the final Proposal Information by clicking on the "Submit Final" button.

C. SOW – 11,400-character limit, including spaces (approximately 2 pages): The SOW is captured as a data field under the "SOW/Abstract" tab in the CDMRP eReceipt system. To submit the SOW, the applicant may either type in the SOW, or electronically cut and paste it from a word processing application into the data field. Sample SOWs can be found at https://cdmrp.org/samples.cfm.

The SOW is a concise restatement of the research proposal that outlines, step by step, how each of the major goals or objectives of the proposed research/services will be accomplished during the timeline for which the USAMRMC will provide financial support.

As appropriate, the SOW should:

- Describe the work to be accomplished as tasks (tasks may relate to specific aims).
- Identify the timeline and milestones for the work over the period of the proposed effort.
- Indicate the numbers of research subjects (animal or human) projected or required for each task.
- Identify methods.
- Identify products/deliverables for each phase of the project.

D. Proposal Abstracts – 5,700-character limit, including spaces (approximately 1 page), for each abstract. Both a structured technical abstract and a public (nontechnical) abstract are required. These abstracts are vitally important to both the peer and programmatic review process.

Programmatic review is based upon the Integration Panel's (IP's) review of these two abstracts as part of the peer review summary statements; therefore, it is paramount that the investigator submit abstracts that fully describe the proposed work.

Each abstract must contain the title of the proposal and the name of the PI. Each abstract must be submitted as a data field under the "SOW/Abstracts" tab of the CDMRP eReceipt system. Applicants can either type in their abstracts, or electronically cut and paste them from a word processing application into the respective data fields. Do not include figures or tables in either abstract. Spell out all Greek or other non-English letters.

Abstracts of all funded proposals will be posted on the CDMRP website at http://cdmrp.army.mil; thus, proprietary or confidential information should not be included in the abstract.

1. Technical Abstract: Sample technical abstracts can be found at https://cdmrp.org/samples.cfm. The structured technical abstract should provide a clear and concise overview of the proposed work, including the background, objective or hypothesis and its supporting rationale, specific aims of the study, study design, and significance of the proposed work to the program's goals.

Use the outline below for preparing the structured technical abstract.

- Background: Provide a brief statement of the ideas and reasoning behind the proposed work.
- Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- Specific Aims: State concisely the specific aims of the study.
- Study Design: Briefly describe the study design.
- Relevance: Provide a brief statement explaining the potential relevance of the proposed work to the program's goals. For example, how the study will cure, prevent, or improve the detection or treatment of the disease.

2. Public Abstract: Sample public abstracts can be found at https://cdmrp.org/samples.cfm. The public abstract is intended to communicate the purpose of, and rationale for, the study to non-scientific audiences. The public abstract is an important component of the proposal review process because consumer advocates, who are part of the review and funding decision process, use this abstract as a part of their review. It must be composed in a way to make the scientific objectives and rationale for the proposal understandable to non-scientifically trained readers. **The public abstract should not be a duplicate of the technical abstract**, but should describe the goals and objectives of the research project, and its relevance to the program.

In addition to describing the project, the public abstract must answer the following questions:

a. What will the ultimate applicability of the research be?

- What types of patients will it help and how?
- What are the potential clinical applications, benefits, and risks?
- What is the projected time it may take to achieve a consumer-related outcome?

b. If the research is too basic for clinical applicability, what are the interim outcomes?

- What types of contributions will this study make to advance research?
- How will the research enhance this or other studies being conducted?

E. Proposal

1. Format: All proposals must be converted into an electronic PDF file for electronic submission. Proposals must be uploaded under the "File Upload" tab of the CDMRP eReceipt system. Applicants unfamiliar with the preparation of PDF files are encouraged to acquire appropriate software and learn the process before the submission deadline. To prepare proposals for PDF submission, the instructions in this subsection must be followed carefully.

The proposal must be clear and legible and conform to the following guidelines:

- Type Font: 12 point, 10 pitch.
- Type Density: No more than 15 characters per inch. (For proportional spacing, the average for any representative section of text should not exceed either 15 characters per inch or 114 characters per line.)
- Spacing: Single-spaced between lines of text, no more than five lines of type within a vertical inch.
- Margins: Minimum of 0.5-inch top, bottom, right, and 1-inch left.
- Color, Resolution, and Multimedia Objects: Proposals may include color, high resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files, but applicants should keep in mind that some reviewers work from black and white printed copies. Applicants may wish to include text in the proposal directing the reviewer to the electronic file for parts of the proposal that may be difficult to interpret when printed in black and white.
- Spell out all acronyms the first time they are used. One page following the proposal body is allocated to spell out acronyms, abbreviations, and symbols.
- Language: English.
- Print Area: 7.0 x 10.0 inches (approximately 18 cm x 25.5 cm).

2. Title/Referral Page: No page limit. Complete the Title/Referral Page, which can be downloaded from the CDMRP website at https://cdmrp.org/programAnnouncements.cfm. Complete each section as described:

a. Proposal title (up to 160 characters).

b. Proposal log number (this will be automatically provided when a draft of the Proposal Information is completed and saved).

c. PI's full name (first, middle initial, last).

d. Submitting Institution.

e. Award mechanism: Type in "Physician-Scientist Training Award."

f. Keyword descriptive technical terms: To assist the staff in assigning proposals to the appropriate scientific peer review panel, please specify the subject area of the proposal. Also, list specific keywords and descriptive technical terms that would best describe the technical aspects of the project.

g. Conflicts of interest: To avoid real and apparent conflicts of interest during the peer review process, list the names of all scientific participants in the proposal including consultants, collaborators, and subcontractors. In addition, list the names of other individuals outside the scope of this proposal who may have a conflict of interest in review of this proposal. Provide the following information for each participant: name, institutional affiliation(s), and role(s) on the proposed project or perceived conflicts of interest.

3. Table of Contents/Checklist: Start section on a new page. Prepare a Table of Contents/Checklist, with page numbers, using the form provided. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. If possible, provide headers throughout the proposal that include the PI's name (last name, first name, middle initial) and proposal log number (this will be automatically provided when a draft of the electronic Proposal Information is saved).

4. Proposal Relevance Statement: Start section on a new page; one-page limit. Applicants should articulate how the combination of training value and relevance to breast cancer will facilitate the applicant's transition to a career in breast cancer clinical research.

5. Main Body: Start section on a new page; 6-page limit inclusive of any figures, tables, graphs, and photographs.

Describe the proposed project using the outline provided below:

- **Training Plans:** Briefly describe the candidate's training plan and how the proposed experience and training will promote the candidate's transition into a career in breast cancer clinical research. Discuss the applicant's career/research plans after the completion of this award.

- **Description of Research Project(s):** The applicant should provide an overview of how his or her time will be spent once relieved from other academic or clinical responsibilities. The following general outline should be used to describe the research project.

- Background: Briefly describe the ideas behind the proposed work and cite relevant literature references.
- Hypothesis/Rationale/Purpose: State the hypothesis that will be tested (in an appropriately designed clinical trial, if applicable) and the expected results.
- Objectives: State concisely the specific aims of the project.
- Methods: Give an overview of the experimental design and methodology including an appropriately powered statistical analysis, if applicable.

6. Abbreviations: Start section on a new page; one-page limit. Provide a list of all acronyms, abbreviations, and symbols used.

7. References: Start section on a new page; no page limit. List all relevant references using a standard reference format that includes the full citation (i.e., author(s), year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

8. Biographical Sketches: Three-page limit per individual. Biographical sketches should be included for each of the key personnel listed on the budget page, including the applicant, the mentor, and collaborating investigators. These documents are a critical component of the review process. Incomplete or missing biographical sketches may result in lower priority scores. The Public Health Service Biographical Sketch form may be used and can be downloaded from the CDMRP website at https://cdmrp.org/programAnnouncements.cfm. Use of this form is not mandatory, but the information requested shall be presented in a similar format.

9. Existing/Pending Support: Start section on a new page; no page limit. Funds for research support are a requirement of the Physician-Scientist Training Award proposal. List on a separate page, the titles, time commitments, supporting agencies, durations, and levels of funding for all existing and pending research projects involving the applicant and mentor. Proposals submitted under this program announcement should not duplicate other funded research projects.

10. Facilities/Equipment Description: No page limit. Describe the facilities available for performance of the proposed research/services. Describe the institutional commitment, including any additional facilities or equipment proposed for purchase or available for use at no cost to the USAMRMC. Indicate if government-owned facilities or equipment are proposed for use.

11. Questionnaires, Survey Instruments, or Clinical Protocols: No page limit. Include an appropriately titled page listing the documents you have included in this section.

12. Publications and/or Patent Abstracts: Five-document limit. Include up to five relevant publication reprints and/or patent abstracts. A patent abstract should provide a non-proprietary description of the patent application. If more than five such items are included in the submission, the extra items will not be peer reviewed.

13. Administrative Documentation: No page limit. Submit only material specifically requested or required in this program announcement. **This section is not for additional data, figures, or other similar information.** Unrequested material that is submitted may be construed as an attempt to gain a competitive advantage and will be removed; it may be grounds for administrative rejection of the proposal.

All administrative documentation must be incorporated into your electronic PDF proposal. Support documentation will not be accepted separately from the electronic proposal submission. All documents or letters requiring signatures must be signed and then incorporated into the proposal prior to submission.

The first item in this section must be a list of all the items included in the Administrative Documentation section. Provide the following in the Administrative Documentation section of the proposal.

a. A Statement of Eligibility Form signed by the Department Chair, Program Director, or Dean indicating that the PI is an eligible applicant for this award type.

b. Proof of US citizenship or permanent resident status (e.g., birth certificate, Permanent Resident Card).

c. A letter of institutional support indicating the level of institutional commitment to fostering the applicant's research career, as reflected by (1) the extent to which the applicant will be relieved of other academic or clinical responsibilities to have additional time for research, (2) the provision of adequate laboratory facilities, and equipment, and (3) opportunities for critical professional interaction with senior colleagues.

d. A letter of support from the mentor describing his or her commitment to the training/career development/mentorship of the applicant.

The mentor should also include the following in his or her letter of support:

- A description of the applicant's potential as a future breast cancer researcher;
- A description of the mentor's interaction in training the candidate;
- A description of the training environment;
- A brief overview of the mentor's clinical research program and plans to incorporate the applicant's training program into this research;
- A description of the mentor's previous experience in training fellows, residents, doctoral students, etc.
- A brief overview of research being performed under the mentor's direction;
- Information on how the mentor can assist in training the applicant for a career in breast cancer research;
- A brief description of the group's resources to demonstrate the adequacy of available support for the trainee and the project (specific details on existing support should be covered in the Existing/Pending Support section; see section V.E.9 above).

e. Letters of support from other collaborating investigators, if applicable.

F. Budget Information: Budget Information includes the Detailed Cost Estimate Form (including Budget Justifications). Budget Information is uploaded under the "File Upload" tab of the CDMRP eReceipt system.

1. Funding Restrictions: The performance period for Physician-Scientist Training Awards will be 5 years. The total support that can be requested over the life of the award is $700,000 inclusive of direct, indirect, and medical school debt reduction costs.

Salary support can be requested for up to 60% of the PI's salary and for up to 50% of a key support person's salary (e.g., a research nurse or a data manager) for 3 years plus indirect costs as appropriate. No salary support will be offered for years 4 and 5 of this award. Training awards frequently have a different institutional indirect charge. Physician-Scientist Training Award applicants are encouraged to check with their institution concerning indirect costs. Direct costs can cover only salary support and travel to scientific meetings. Funds for other research expenses must be provided from another resource (e.g., a grant to the mentor). The amount allotted for travel is $1,800 per year to attend scientific/technical meetings. In addition, funding should be requested for a one-time, 3½-day meeting in 2005 to disseminate the results of DOD-sponsored research.

In addition, the Physician-Scientist Training Award offers a medical school debt reduction incentive. Up to $40,000 per year (representing no more than the actual loan repayments made by the PI during the year) can be requested for repayment of qualifying medical school education loans over the 5-year performance period of the award. Upon completion of the 5-year commitment to clinical breast cancer research, an additional payment will be made to cover the remainder of the medical school education loan(s), up to a total of $200,000 for loan repayment over the 5-year period. For example, a PI with a total medical school education loan of $100,000 principal and annual payments of $18,000 would receive $18,000 per year for the 5 years of the award. Just prior to the end of the performance period, an additional payment equal to the remaining debt of the original loan (up to $200,000) would be made. The institution to which the award is made will be reimbursed for payments made by the applicant for his or her current medical school loans. Qualifying loans include funds borrowed from the government, academic institutions, or commercial lenders for medical school tuition expenses at an accredited US medical or osteopathic school, additional educational expenses (e.g., textbooks, supplies, fees), and reasonable living expenses. Certain loans do not qualify for repayment under this award, including loans from individuals or any loan that has been consolidated with that of another individual and loans already being repaid from another award source. Include the total amount of eligible medical school education loans and yearly payments in the budget estimate. Additional loan documentation will be required and final decisions regarding qualification of a loan for repayment will be made at the time of award negotiation.

2. Detailed Cost Estimate Form (including Budget Justifications) Instructions: Budget is an important consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. Budgets will also be reviewed during award negotiations. Complete justification must be provided for expenses in all categories. The Detailed Cost Estimate Form (including Budget Justifications) for your proposal must be uploaded as a PDF file, separate from the proposal.

The following section provides instructions for preparing the Detailed Cost Estimate Form. All amounts entered should be in US dollars.

a. Personnel

i. Name: Starting with the PI, list the names of all participants who will be involved in the project during the initial budget period, regardless of whether salaries are requested. Include all collaborating investigators, research associates, individuals in training, and support staff. Only **ONE** person may be identified as the PI of the proposal.

ii. Role on Project: Identify the role of each individual listed on the project. Describe his or her specific functions in the Budget Justifications section of the Detailed Cost Estimate Form.

iii. Type of Appointment (Months): List the number of months per year reflected in an individual's contractual appointment with the applicant organization. The DOD staff assumes that appointments at the applicant organization are full time for each individual. If an appointment is less than full time, e.g., 50 percent, note this with an asterisk (*) and provide a full explanation in the "Justification" section of the Detailed Cost Estimate Form. Individuals may have split appointments (e.g., for an academic period and a summer period). For each type of appointment, identify and enter the number of months on separate lines.

iv. Annual Base Salary: Enter the annual institutional base salary for each individual listed for the project.

v. Percentage of Effort on Project: The qualifications of the PI and the amount of time that he or she and other professional personnel will devote to the research are important factors in selecting research proposals for funding. For each key staff member identified on the budget form, list the percentage of each appointment to be spent on this project.

vi. Salaries Requested: Enter the salaries in whole dollar figures for each position for which funds are requested. The salary requested is calculated by multiplying an individual's institutional base salary by the percentage of effort on the project.

vii. Fringe Benefits: Fringe benefits may be requested in accordance with institutional guidelines for each position, provided the costs are treated consistently by the applicant's organization. A copy of the rate agreement or other documentation to support the fringe benefits should be provided.

viii. Totals: Calculate the totals for each position and enter these as subtotals in the columns indicated.

b. Consultant Costs: Regardless of whether funds are requested, provide the names and organizational affiliations of all consultants.

c. Major Equipment: It is the policy of the DOD that all commercial and non-profit recipients provide the equipment needed to support proposed research. In those rare cases where specific additional equipment is approved for commercial and non-profit organizations, such approved cost elements shall be separately negotiated.

d. Materials, Supplies, and Consumables: A general description and total estimated cost of expendable equipment and supplies are required. Itemize supplies in separate categories (e.g., glassware, chemicals, radioisotopes). Categories with amounts less than $1,000 do not need to be itemized. If animals are to be purchased, state the species, strain (if applicable), and the number to be used. If human cell lines are to be purchased, state the source and the description

e. Travel Costs: Travel costs may not exceed $1,800 per year to attend scientific/technical meetings. In addition, funding should be requested for a one-time, 3½-day meeting in 2005 to disseminate the results of DOD-sponsored research.

f. Research-Related Subject Costs: Itemize costs of subject participation in the research study. These costs are strictly limited to expenses specifically associated with the proposed study. The USAMRMC will not provide funds for ongoing medical care costs that are not related to a subject's participation in the research study.

g. Other Expenses: Itemize other anticipated direct costs such as publication and report costs, rental for computers and other equipment (provide hours and rates), and communication costs. Unusual or expensive items should be fully explained and justified. Estimate the costs of publishing and reporting research results, including direct charges for clerical preparation, illustrations, reprints, and distribution.

h. Subcontract Costs: A description of services or materials that are to be awarded by subcontract or sub-grant is required. For awards totaling $10,000 or more, provide the following specific information:

- Identification of the type of award to be used (e.g., cost reimbursement, fixed price).
- Identification of the proposed subcontractor or sub-grantee, if known, and an explanation of why and how the subcontractor or sub-grantee was selected or will be selected.
- Whether the award will be competitive and, if noncompetitive, rationale to justify the absence of competition.
- The proposed acquisition price.

i. Indirect Costs (overhead, general and administrative, and other): The most recent rates, dates of negotiation, base(s), and periods to which the rates apply should be disclosed along with a statement identifying whether the proposed rates are provisional or fixed.

j. Total Costs for the Entire Proposed Period of Support (second page of the Detailed Cost Estimate Form): Enter the totals under each budget category for all additional years of support requested and itemize these totals in the Budget Justifications section of the Detailed Cost Estimate Form. Note with an asterisk (*) and explain any significant increases or decreases from the initial year budget. All amounts should be in US dollars. Total costs for the entire proposed period of support should agree with the amount previously entered online in the Proposal Information https://cdmrp.org/proposals.

3. Justification (third page of the Detailed Cost Estimate Form): Each item in the budget should be clearly justified under the Budget Justifications section of the Detailed Cost Estimate Form.

G. RCQ Requirements: Completed and signed copies of the Certificate of Environmental Compliance and Principal Investigator Safety Program Assurance Form must be uploaded under the "File Upload" tab of the CDMRP eReceipt system as separate PDF files.

Do not submit other RCQ Documents (Research Involving Human Subjects and/or Anatomical Substances; Research Involving Animals) with the proposal. Instead, the applicant should provide these documents to the USAMRMC only upon request.

H. USAMRAA Documents: A copy of the institution's negotiated Rate Agreement, the Certifications and Assurances for Assistance Agreements, and the Representations for Assistance Agreements must be uploaded by the Contract Representative from the Sponsored Programs Office. These documents must be uploaded as separate PDF files under the Contract Representative "My Profile" tab of the CDMRP eReceipt system.

I. Submission Dates and Times: Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant's institution's Sponsored Programs Office (or equivalent) by the

deadline. If your proposal is submitted and approved electronically after the deadline, it will not be considered for review.

The timeline for Physician-Scientist Training Awards is:

Online Letter of Intent:	As soon as possible but no later than April 16, 2003.
Online Proposal Information:	Prior to proposal submission.
Proposal Submission/Approval Deadline:	**5:00 p.m. Eastern time May 14, 2003.**
Peer Review:	July/August 2003.
Programmatic Review:	November 2003.
Request for Additional Documents:	As early as 2 weeks after the completion of programmatic review.
Notification Letter:	Approximately 4 weeks after programmatic review.
Award Start Date:	Between December 2003 and September 2004.

J. Electronic Submission Requirements: Electronic submission is required. Proposals will be accepted only as PDF files submitted through the CDMRP eReceipt system at https://cdmrp.org/proposals.

Several steps are critical to successful proposal submission.

- The Proposal Information must be submitted prior to submission of the proposal. Applicants are encouraged to begin this part of the submission process early.
- The e-mail address of a Contract Representative from the Sponsored Programs Office must be included.
- Applicants are encouraged to coordinate early with their Sponsored Programs Office.
- The Contract Representative from the Sponsored Programs Office who is authorized to negotiate on behalf of the institution is required to provide final approval before the proposal is accepted.
- **If final approval is not accomplished by the submission deadline, the proposal will be considered a "LATE" submission and will not be considered for review.**
- Any supporting documentation that the applicant includes with the proposal must be incorporated into the PDF file prior to upload.
- Some items to be included in the proposal will need to be scanned. These items might include figures, tables, letters, or publications. All scanned documents including figures should be scanned at a resolution of 300-400 dpi or less.
- Budget Information includes the Detailed Cost Estimate Form (including Budget Justifications). Budget Information must be uploaded under the "File Upload" tab of the CDMRP eReceipt system.
- The RCQ documents required at submission include a completed, signed Certificate of Environmental Compliance and a completed, signed PI Safety Program Assurance Form. These must be uploaded under the "File Upload" tab of the CDMRP eReceipt system.

VI. PROPOSAL REVIEW INFORMATION

A. Proposal Review and Selection Overview

1. Process: The CDMRP uses a two-tiered review process for proposal evaluation. The two tiers are fundamentally different. The first tier is a scientific peer review of proposals against established criteria

for determination of scientific merit. The second tier is a programmatic review of proposals that compares submissions to each other and recommends proposals for funding based on scientific merit as well as overall program goals.

2. Peer Review: Peer review is conducted by panels organized according to scientific discipline or specialty area. The primary responsibility of the peer review panels is to provide unbiased, expert advice on the scientific/technical merit and relevance of proposals, based upon the review criteria published for each award mechanism.

Peer review panels are composed of a chair, scientific reviewers, consumer reviewers, and a nonvoting executive secretary. Scientific reviewers are selected based on their expertise and their experience with scientific peer review. Consumer reviewers are nominated by an advocacy or support organization and are selected on the basis of their leadership skills, commitment to advocacy, and interest in science. Consumers augment the peer review by bringing the patient perspective to the assessment of science and to the relevance of research.

Panel members rate each proposal based on specific evaluation criteria developed for each award mechanism (see section VI.B.). Two types of ratings are used. First, each of the evaluation criteria, except for the budget, is rated on a scale of 1 (lowest merit) to 10 (highest merit). This criteria scoring ensures that each component is considered in peer review. Second, the overall proposal is given a global priority score using a scale of 1 (highest merit) to 5 (lowest merit). Criteria scores are neither averaged nor mathematically manipulated to determine the global priority score. Instead, reviewers are asked to use the criteria scores as a guide in determining the global priority score. In rare instances, a proposal may be disapproved at peer review if gravely hazardous or unethical procedures are involved, or if the proposal is so seriously flawed that its completion is implausible.

The peer review summary statement is a product of scientific peer review. Each summary statement includes the peer review scores, and an evaluation of the project as assessed by the peer reviewers according to the evaluation criteria published in this program announcement.

3. Programmatic Review: The second tier is programmatic review. Programmatic review is accomplished by the IP, which is composed of scientists, clinicians, and consumer advocates. The scientific members of the IP represent diverse disciplines and specialty areas, and the consumer members represent national advocacy constituencies. One of the functions of programmatic review is to select a broad portfolio of grants across all disciplines. Programmatic review is a comparison-based process in which proposals from multiple research areas compete in a common pool. IP members primarily use the peer review summary statements and the proposal abstracts; SOWs may also be reviewed. Full proposals are not forwarded to programmatic review.

HBCU/MI proposals will be reviewed concurrently with all others in the same research area during scientific peer review, but may be evaluated separately during programmatic review. Consistent with the CDMRP's goal, recommendations for funding HBCU/MI submissions will be based upon scientific excellence and program relevance.

B. Review Criteria

1. Peer Review: Physician-Scientist Training Award proposals will be evaluated according to the following criteria:

- **Candidate:** Does the candidate have the appropriate background to pursue a career in breast cancer clinical research? Do the candidate's previous training and prior research experience

indicate promising achievements to date? Is there a need for the proposed research experience and training in order for the candidate to develop into an independent breast cancer investigator?

- **Potential for a Career in Breast Cancer Clinical Research:** Has the candidate demonstrated how his or her qualifications, the mentor, the training environment, the quality of research training, and the project's scientific relevance will lead to a career in breast cancer clinical research? Has the candidate demonstrated a personal commitment to pursuing a career in breast cancer clinical research?
- **Mentor:** Does the mentor have the background, qualifications, research resources, and time to supervise the candidate's training program? What is the mentor's previous research training experience with doctoral students, fellows, residents, etc.? Does the mentor have an established cancer research program with an emphasis on clinical breast cancer research?
- **Clinical Research Training Program:** Is there a clearly described training program in breast cancer clinical research? Does the training program include key clinical research areas such as statistics, bioethics, molecular biology and clinical trials design? Are the conceptual framework, hypotheses, design, methods, and analyses of the research adequately developed and well integrated for the candidate's research program? Is the candidate aware of potential problem areas, and are potential solutions proposed? Will the research offer a valuable opportunity to further develop research experience to advance and develop the candidate's independent clinical breast cancer research career?
- **Disease Relevance:** Does the candidate's research program address a critical problem in breast cancer research? Does the application make a convincing case for the relevance of the research to breast cancer? To what extent will the project, if successful, make an original and important contribution to the goal of preventing or eradicating breast cancer and/or advancing research in the field?
- **Institutional Commitment:** Is there a strong institutional commitment to relieve the candidate from other academic or clinical responsibilities in order to permit a minimum of 60% effort for research activities? Is the institution prepared to provide adequate laboratory facilities, equipment, and opportunities for critical professional interaction with senior colleagues? Is there a strong institutional commitment to the candidate's development?
- **Budget:** Is the budget appropriate?

2. Programmatic Review: The ratings and evaluations of scientific peer review panels are primary factors in programmatic review. The IP also considers other criteria to establish the BCRP's broad portfolio. The criteria the IP uses to make funding recommendations are:

- Ratings and evaluations of the scientific peer review panels.
- Programmatic relevance.
- Relative innovation.
- Program portfolio balance with respect to research disciplines or specialty areas.
- Adherence to award mechanism and programmatic review criteria.

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program are selected by the IP and recommended to the Commanding General, USAMRMC, for funding.

VII. AWARD ADMINISTRATION INFORMATION

A. Award Notices: After the two-tiered evaluation process is completed, every applicant will receive notification of the award status of his or her proposal and a copy of the peer review summary statement. Applicants can expect to be notified of the agency's decision in December 2003.

B. Administrative Requirements: All awards are made to organizations, not individuals. A PI should submit a proposal through, and be employed by or affiliated with, a university, college, non-profit research institute, commercial firm, or government agency (including military laboratories) in order to receive support. To be eligible for award, a prospective recipient should meet certain minimum standards pertaining to institutional support, financial resources, prior record of performance, integrity, organization, experience, operational controls, facilities, and conformance with safety and environmental statutes and regulations (Office of Management and Budget Circular A-110).

Any change in the institution, the PI, and/or the SOW will require that the PI resubmit contact information. Any delay in the submission of updated information could result in a delay in the contracting and regulatory review and a subsequent delay in payment.

C. Award Negotiation: Award negotiation consists of discussions, reviews, and justifications of critical issues involving the USAMRAA. A Contract Specialist from USAMRAA will contact the Contract Representative from the Sponsored Programs Office (or equivalent) who is authorized to negotiate contracts and grants at the applicant's institution. As part of the negotiation process, additional documentation and justifications related to the proposed SOW and associated budgets may be required.

Note that the award start date will be determined during the negotiation process.

D. Regulatory Compliance and Quality Review

1. Overview: Concurrent with the USAMRAA negotiations, Regulatory Compliance and Quality will review the Certificate of Environmental Compliance, and PI Safety Program Assurance form submitted with the proposal, as well as Regulatory Compliance and Quality documents related to Research Involving Animal Use and Research Involving Human Subjects/Anatomical Substance Use submitted upon request to ensure that Army regulations are met.

2. Certificate of Environmental Compliance: The Certificate of Environmental Compliance should be submitted with the proposal. If multiple research sites/institutions are funded in your proposal, then a Certificate of Environmental Compliance for each site will be requested at a later date.

3. Safety Program Documents: The Principal Investigator Safety Assurance Form should be submitted with the proposal.

A Facility Safety Plan is also required and will be requested at a later date. However, your institution may already have an approved Facility Safety Plan. To determine the status of approval, check the USAMRMC website at http://mrmc-www.army.mil/crprcqsohdfsplan.asp. If your institution is not listed on the aforementioned website, contact your Facility Safety Director/Manager to initiate completion of the institution-based Facility Safety Plan. Specific requirements for the Safety Program Plan can be found at http://mrmc-www.army.mil/docs/rcq/FY02FSPAppendix.doc .

If multiple research sites/institutions are funded in your proposal, then a Facility Safety Plan for each site/institution not listed in the aforementioned website will be requested at a later date.

4. Research Involving Animal Use: Animal use documents should not be submitted with the proposal and will be requested at a later date. Specific requirements for research involving animals can be found at http://mrmc-www.army.mil/docs/rcq/FY02AnimalAppendix.doc.

5. Research Involving Human Subjects/Anatomical Substances: Human Subjects and/or Anatomical Substances use documents should not be submitted with the proposal and will be requested at a later date. In addition to local Institutional Review Board approval to conduct research involving human subjects and/or anatomical substances, a second tier of review and approval is also required by the DOD. This second review is conducted by the Human Subjects Research Review Board (HSRRB), which is administered by the USAMRMC Office of Regulatory Compliance and Quality. The HSRRB is mandated to comply with specific laws and directives governing all research involving human subjects that is conducted or supported by the DOD. These laws and directives are rigorous and detailed and will require information in addition to that supplied to the local review board. For example:

- Intent to Benefit. In the development of a research protocol for submission to the DOD, the applicant must specifically address, if applicable, the Intent to Benefit. An individual not legally competent to consent (e.g., minors) may not be enrolled in DOD-sponsored research unless the research is intended to benefit each and every subject enrolled in the study. Applicants should be aware that this law makes placebo-controlled clinical trials problematic because of the 'Intent to Benefit' requirement whenever participation is sought of subjects from whom consent must be obtained by the legally authorized representative.
- The DOD considers cell lines of human origin to be human anatomical substances. Use of these cell lines is subject to HSRRB review and approval.

Specific requirements for research involving human subjects and/or anatomical substances can be found at http://mrmc-www.army.mil/docs/rcq/HSAppendix19Feb02.pdf. An informed consent form template can be located at http://mrmc-www.army.mil/docs/rcq/consentform_template.pdf.

E. Reporting: All research awards will require the timely delivery of several reports during the research effort. Reporting requirements consist of an annual report (for each year of research except the final year) that presents a detailed summary of scientific issues and accomplishments and a final report (submitted in the last year of the award period) that details the findings and issues for the entire project.

VIII. OTHER INFORMATION

A. Disclosure of Proprietary Information outside the Government: By submission of a proposal, the applicant understands that proprietary information may be disclosed outside the Government for the sole purpose of technical evaluation. The USAMRMC will obtain a written agreement from the evaluator that proprietary information in the proposal will only be used for evaluation purposes and will not be further disclosed or utilized. Funded proposals may be subject to public release under the Freedom of Information Act; proposals that are not selected for funding will not be subject to public release.

B. Government Obligation: Applicants are cautioned that only an appointed Contracting/Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government to fund preparation of a proposal or to support research should be inferred from discussions with a technical project officer. Applicants who, or organizations that make financial or other commitments for a research

effort in the absence of an actual legal obligation signed by the USAMRAA Contracting/Grants Officer do so at their own risk.

C. Information Service: Offerors may use the technical reference facilities of the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia, 22161, for the purpose of surveying existing knowledge and avoiding needless duplication of scientific and engineering effort and the expenditure thereby represented. To the extent practical, all other sources should also be consulted for the same purpose.

D. Inquiry Review Panel: Applicants can submit a letter of inquiry to the USAMRMC in response to funding decisions made for a given proposal. Members of the CDMRP staff, USAMRMC Judge Advocate General staff, and USAMRAA Grants Officers constitute an Inquiry Review Panel and review each inquiry to determine whether factual or procedural errors in either peer or programmatic review have occurred, and if so, what action should be taken.

E. Title to Inventions and Patents: In accordance with the Bayh-Dole Act (35 USC 200 et seq.[2]), title to inventions and patents resulting from such federally funded research may be held by the grantee or its collaborator, but the US Government shall, at a minimum, retain nonexclusive rights for the use of such inventions. An investigator must follow the instructions in the assistance agreement concerning license agreements and patents.

[2] Title 35, United States Code, Section 200 et seq.